UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

JONNIE HOMYK, et al.,

Plaintiffs,

v.

CHEMOCENTRYX, INC., et al.,

Defendants.

Case No. 21-cv-03343-JST

ORDER GRANTING IN PART AND DENYING IN PART MOTION TO DISMISS

Re: ECF No. 50

Now before the Court is ChemoCentryx, Inc. and Dr. Thomas J. Schall's ("Defendants") motion to dismiss the amended consolidated class action complaint ("CAC"). ECF No. 50. The Court will grant the motion in part and deny it in part.

I. BACKGROUND

Lead Plaintiff Indiana Public Retirement System brings this action individually and on behalf of all persons who purchased or otherwise acquired ChemoCentryx common stock between November 26, 2019, and May 6, 2021, inclusive ("Class Period"). For the purposes of resolving the present motion, the Court accepts as true the factual allegations in the CAC, ECF No. 47.

Plaintiff alleges that ChemoCentryx and Dr. Schall, its President and Chief Executive Officer, violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and U.S. Securities and Exchange Commission Rule 10b-5 by making false and misleading statements and omissions about the safety, efficacy, and application for FDA approval of a proprietary vasculitis drug called avacopan, thereby artificially inflating the price of ChemoCentryx stock during the Class Period. Plaintiff also alleges that Dr. Schall is liable for insider trading under Section 20A of the Securities Exchange Act.

ChemoCentryx is a pharmaceutical company specializing in drugs designed to treat rare

diseases. During the Class Period, ChemoCentryx had four drug candidates in its research and development pipeline. The most promising of these drugs was avacopan, which Defendants presented as a breakthrough therapy for the treatment of ANCA-associated vasculitis, a rare autoimmune disease. The standard of care for treatment of ANCA-associated vasculitis involves a combination of corticosteroids and immunosuppressants. Long-term steroid use presents safety risks for patients. Defendants described avacopan as a drug that would transform the standard of care for ANCA-associated vasculitis, in part by replacing steroid treatment.

Before and during the Class Period, ChemoCentryx had no approved drugs on the market and therefore generated no sales revenue. ChemoCentryx operated at a loss and relied on capital raised from investors to fund research and development. Avacopan, the drug furthest along in development, was critical to the company's future financial success. Industry analysts focused their valuations of the company on the promise of the drug, and investor confidence in avacopan was essential to ChemoCentryx's continued operation.

At the start of the Class Period, Defendants announced the results of the Phase III trial of avacopan for the treatment of ANCA-associated vasculitis. The avacopan trial was designed to provide evidence to support ChemoCentryx's application for Food and Drug Administration ("FDA") approval of avacopan. Throughout the Class Period, Defendants stated that trial safety results showed that avacopan was safer than standard-of-care steroid therapy; that, in the trial, avacopan had demonstrated non-inferiority versus prednisone with respect to the primary endpoint of Birmingham Vasculitis Activity Score ("BVAS") remission at week 26 and superiority at week 52; that the study demonstrated that chronic steroids were not needed to achieve remission; and that communications with the FDA regarding the avacopan New Drug Application ("NDA") had been straightforward. Defendants also stated that avacopan had "'$1 billion-plus revenue potential per year' in the United States alone." ECF No. 47 ¶ 5.

However, in private communications with Defendants in 2016 and 2020, the FDA had expressed concerns about the trial's design and results. The FDA told Defendants that their proposed study design was inadequate to support a comparison of the relative safety of avacopan and steroid therapy. The FDA warned that statistical non-inferiority in remission would be

inadequate to demonstrate that avacopan could replace steroid therapy – superiority would be required. The FDA further warned Defendants that the trial's relapse results did not provide empirically sound evidence of efficacy and that steroid use among the avacopan patients in the trial would complicate interpretation of trial results. The agency also suggested that subgroup data raised questions about the meaning of the study's result and that, in light of these issues an Advisory Committee Meeting might be needed to evaluate the trial results.

Defendants knowingly withheld adverse facts from investors during the Class Period. First, Defendants knew that the trial results could not support their claims about the safety of avacopan due to trial design issues the FDA had identified in private communications. Additionally, Defendants knew of and failed to disclose serious adverse liver events, including an event meeting Hy's Law criteria[1] and one occurring after rechallenge[2], that occurred during the trial. A confidential former employee stated that Catherine Kelleher – then the company's most senior medical executive – repeatedly raised these two adverse liver events with other company executives, including Dr. Schall, who acknowledged that the events were "problematic." ECF No. 47 ¶ 128. Further, ChemoCentryx failed to follow trial protocol in calculating remission results: when the results were later calculated in accordance with trial protocol, avacopan failed to achieve superiority to standard-of-care steroid therapy at week 52 by a statistically significant margin.[3] Additionally, as Defendants knew, steroid use was significant and widespread among avacopan patients enrolled in the trial. The majority of avacopan patients were prescribed prednisone during the trial to control their vasculitis, and ChemoCentryx considered such patients to have responded

[1] "As FDA guidance explains, satisfaction of Hy's Law criteria is '*an ominous indicator*' of the potential for a drug to cause serious liver injury." *Id.* ¶ 125 (emphasis in original) (quotation marks in original without attribution).

[2] The complaint explains that rechallenge is the process of readministering a drug to a patient who had previously been taken off the drug because of an adverse event. *Id.* ¶ 125. For instance, one avacopan patient had a serious adverse event involving hepatocellular injury with increase in liver enzymes – an issue flagged in clinical development – after being readministered avacopan, having already been taken off the drug because of a previous adverse event that investigators suspected was caused by the drug (a process called "rechallenge").

[3] When calculated according to trial protocol, avacopan was merely non-inferior to prednisone, a result the FDA had previously warned would be insufficient to show that avacopan could replace steroid therapy.

to avacopan in its analysis of trial data, despite their significant steroid use. Defendants knew that these adverse facts undermined their public statements about the comparative safety and efficacy of avacopan and standard-of-care steroid therapy.

Defendants' misleading statements about the success of the avacopan trial and the prospective NDA submission artificially inflated ChemoCentryx's stock price during the Class Period, enriching both Dr. Schall and ChemoCentryx. During the 17-month Class Period, Dr. Schall sold more than 893,300 shares of ChemoCentryx stock – representing nearly 20% of his ChemoCentryx holdings – and earned proceeds of over $40.3 million. This was nearly four times as much stock as he had sold in the preceding 17-month period ("Control Period"). In June 2020, ChemoCentryx held a $325 million public offering, the largest in its history. Because ChemoCentryx required investor funding to continue operations until avacopan was approved, this financing was critical to the company's survival.

The market learned the extent of the FDA's concerns about the trial in early May 2021. On May 4, the FDA published the Briefing Book and slides in advance of its Advisory Committee meeting. The concerns reflected in the Advisory Committee materials mirrored the concerns the FDA had privately expressed to ChemoCentryx in 2016 and 2020. The Advisory Committee materials revealed that the FDA had previously raised these concerns to ChemoCentryx and described the extent of steroid use among avacopan patients in the trial. In response to the release of the Advisory Committee materials, ChemoCentryx's stock dropped more than 45% in a single day. Analysts and investors expressed surprise at the scope of the FDA's criticism of the trial and the fact that ChemoCentryx had known of, but not disclosed, the FDA's concerns.

On May 6, 2021, the Advisory Committee held a public meeting to discuss avacopan. Advisory Committee members were evenly split on the question of whether the drug should be approved, and those who voted in favor of approval argued its label should be limited – that is, that it should only be approved for use by a limited set of patients.

Overall, ChemoCentryx's share price fell 79% over four days, from $48.82 on May 3, 2021, to $10.46 on May 7, 2021. This caused massive losses to investors, including Plaintiff. The FDA ultimately approved avacopan for use only in conjunction with steroids and only by

adult patients with severe active ANCA-associated vasculitis. The FDA also required ChemoCentryx to include warnings for liver toxicity on the avacopan label and ordered ChemoCentryx to conduct three post-marketing studies to evaluate liver toxicity.

Multiple shareholders filed class action complaints, which were consolidated into a single action. ECF No. 32. Plaintiff filed the operative CAC on March 28, 2022. ECF No. 47. On May 19, 2022, Defendants filed the instant motion to dismiss, arguing that Plaintiff's "puzzle pleading" fails to specifically identify each allegedly false or misleading statement as required by Section 10(b); that Plaintiff fails to sufficiently plead falsity under the Private Securities Litigation Reform Act ("PSLRA"); that Plaintiff has not pleaded a strong inference of scienter, as required by the PSLRA and Federal Rule of Civil Procedure 9(b); and that Plaintiff's Section 20(a) and 20A claims fail as a matter of law. ECF No. 50.

II. JURISDICTION

The Court has jurisdiction under 28 U.S.C. § 1331.

III. LEGAL STANDARD

Section 10(b) prohibits any act or omission resulting in fraud or deceit in connection with the purchase or sale of any security. "To plead a claim under [S]ection 10(b) and Rule 10b-5, the Plaintiff must allege: (1) a material misrepresentation or omission; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation." *City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Align Tech., Inc.*, 856 F.3d 605, 613 (9th Cir. 2017) (quoting *Or. Pub. Emps. Ret. Fund v. Apollo Grp. Inc.*, 774 F.3d 598, 603 (9th Cir. 2014)).

To survive a motion to dismiss, a plaintiff must plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007). The Court must "accept all factual allegations in the complaint as true and construe the pleadings in the light most favorable to the [plaintiff]." *Knievel v. ESPN*, 393 F.3d 1068, 1072 (9th Cir. 2005). However, "the tenet that a court must accept a complaint's allegations as true is inapplicable to threadbare recitals of a cause of action's elements, supported by mere conclusory statements." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

"Securities fraud class actions must [also] meet the higher, exacting pleading standards of Federal Rule of Civil Procedure 9(b) and the [PSLRA]." *Oregon Pub. Emps Ret. Fund*, 774 F.3d at 604. Under Rule 9(b) and the PSLRA, a complaint must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind" with respect to the alleged false statements or omissions, and a party must "state with particularity the circumstances constituting fraud or mistake." 15 U.S.C. § 78u–4(b)(2)(A); Fed. R. Civ. P. 9(b). If the complaint does not satisfy the PSLRA's pleading requirements, the Court must grant a motion to dismiss the complaint. 15 U.S.C. § 78u–4(b)(3)(A).

IV. DISCUSSION

A. Judicial Notice and Incorporation by Reference

Defendants request that the Court either take judicial notice of or consider twenty-nine documents under the incorporation-by-reference doctrine. Plaintiff does not oppose the request.

1. Judicial Notice

Defendants request that the Court take judicial notice of the following five documents.

ECF No.	Description
52-2	"Evaluation of the Safety and Efficacy of Avacopan, a C5a Receptor Inhibitor, in Patients with Antineutrophil Cytoplasmic Antibody-Associated Vasculitis Treated Concomitantly with Rituximab or Cyclophasphamide/Azathrioprine," published on April 4, 2020, in *Journal of Medical Internet Research*
52-18	ChemoCentryx Stock Price, May 5, 2021 - October 29, 2021
52-20	FDA Guidance Document on Drug Safety Terms
52-21	ERA-EDTA Conference Abstract, June 7, 2020
52-22	EULAR Conference Transcript, June 3, 2020

Federal Rule of Evidence 201 permits a court to notice an adjudicative fact if it is "not subject to reasonable dispute." Fed. R. Evid. 201(b). A fact is "not subject to reasonable dispute" if it is "generally known," or "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b)(1)-(2). "Accordingly, '[a] court may take judicial notice of matters of public record without converting a motion to dismiss into a

motion for summary judgment[,]'" "[b]ut a court cannot take judicial notice of disputed facts contained in such public records." *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 999 (9th Cir. 2018) (quoting *Lee v. City of Los Angeles*, 250 F.3d 668, 689 (9th Cir. 2001)).

The Court will take judicial notice of the journal article filed at ECF No. 52-2 for the purpose of determining what information was available to the market. *See, e.g.*, *Von Saher v. Norton Simon Museum of Art at Pasadena*, 592 F.3d 954, 960 (9th Cir. 2009) ("Courts may take judicial notice of publications introduced to 'indicate what was in the public realm at the time, not whether the contents of those articles were in fact true.'") (quoting *Premier Growth Fund v. All. Cap. Mgmt.*, 435 F.3d 396, 401 n.15 (3d Cir. 2006)); *In re Facebook, Inc. Sec. Litig.*, 405 F. Supp. 3d 809, 828 (N.D. Cal. 2019) (taking judicial notice of publicly available publications for the same purpose).

The Court will take judicial notice of historical stock price data, ECF No. 52-18. Courts may take judicial notice of stock prices because they "are not subject to reasonable dispute" and "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." *In re Atossa Genetics Inc Sec. Litig.*, 868 F.3d 784, 799 (9th Cir. 2017); *see also In re Facebook, Inc. Sec. Litig.*, 405 F. Supp. 3d at 828 (taking judicial notice of historical stock prices).

The Court will take judicial notice of the FDA guide to drug safety terms, ECF No. 52-20. Government publications that are publicly available on agency websites, including FDA guidance documents, are properly subject to judicial notice. *Allen v. ConAgra Foods, Inc.*, No. 13-cv-01279-WHO, 2018 WL 6460451, at *8 n.6 (N.D. Cal. Dec. 10, 2018).

The Court will take judicial notice of abstracts of ChemoCentryx's presentations at two scientific conferences during the Class Period, ECF Nos. 52-21 & 52-22, for the purpose of determining what information was available to the market. *See Bodri v. GoPro, Inc.*, 252 F. Supp. 3d 912, 921 (N.D. Cal. 2017) (taking judicial notice of transcripts of conference presentations).

2. Incorporation by Reference

Defendants request that the Court find the following 24 documents incorporated in the CAC by reference.

ECF No.	Description
52-1	ChemoCentryx's Form 10-K for the period ending December 31, 2020, filed March 1, 2021
52-3	FDA Meeting Minutes, November 1, 2016
52-4	"Avacopan for the Treatment of ANCA-Associated Vasculitis," published February 18, 2021, in *The New England Journal of Medicine*, including the Trial Protocol
52-5	FDA Meeting Minutes, July 14, 2016
52-6	ChemoCentryx's Form 8-K, filed November 25, 2019
52-7	Q3 2020 Earnings Call Transcript, November 9, 2020
52-8	ChemoCentryx's Form 10-K for the period ending December 31, 2019, filed March 10, 2020
52-9	ChemoCentryx's Form 10-Q for the period ending March 31, 2020, filed May 11, 2020
52-10	ChemoCentryx's Form 10-Q for the period ending June 30, 2020, filed August 10, 2020
52-11	ChemoCentryx's Form 10-Q for the period ending September 30, 2020, filed November 9, 2020
52-12	ChemoCentryx Announces Acceptance of NDA, Press Release, September 17, 2020
52-13	J.P. Morgan Investor Conference, January 13, 2021
52-14	ChemoCentryx R&D Day, April 14, 2021
52-15	Q1 2021 Earnings Call Transcript, April 29, 2021
52-16	FDA Briefing Book, published May 6, 2021
52-17	Advisory Committee Transcript, May 6, 2021
52-19	FDA Approved TAVNEOS (avacopan) label, published October 8, 2021
52-23	Q3 2019 Earnings Call Transcript, November 4, 2019
52-24	FDA Meeting Minutes, March 19, 2020
52-25	H.C. Wainwright Analyst Advocate Analyst Report, November 26, 2019
52-26	Investor Call Transcript, November 25, 2019
52-27	Thomas Schall Form 4s for the period between November 26, 2019, and May 6, 2021

ECF No.	Description
52-28	Q2 2020 Earnings Call Transcript, August 10, 2020
52-29	2020 Earnings Call Transcript, March 1, 2021

A document is incorporated by reference where the complaint "refers extensively to the document or the document forms the basis of the plaintiff's claim." *Khoja*, 899 F.3d at 1002 (quoting *United States v. Ritchie*, 342 F.3d 903, 907 (9th Cir. 2003)). "[T]he mere mention of the existence of a document is insufficient to incorporate [its] contents." *Coto Settlement v. Eisenberg*, 593 F.3d 1031, 1038 (9th Cir. 2010). Unlike with judicial notice, the Court may assume the contents of incorporated documents are true, though not for the sole purpose of disputing facts in a well-pleaded complaint. *Khoja*, 899 F.3d at 1003.

The Court finds the documents filed at ECF Nos. 52-1, 52-3, 52-4, 52-5, 52-6, 52-7, 52-8, 52-9, 52-10, 52-11, 52-12, 52-13, 52-14, 52-15, 52-16, 52-17, 52-19, 52-24, 52-25, 52-26, 52-27, 52-28, and 52-29 incorporated by reference because these documents are referred to extensively in the CAC and form the basis of Plaintiff's claims. Plaintiff does not dispute the authenticity of any of these documents, each of which the CAC references repeatedly. Plaintiff alleges that each document either contains false or misleading statements, proves scienter, or demonstrates reliance. Because each document forms the basis for a necessary element of Plaintiff's claims, each is properly incorporated by reference. *See Khoja*, 899 F.3d at 1002.

However, the Court finds that the document filed at ECF No. 52-23 is not properly incorporated by reference. This document is only referred to once in the CAC and serves only to explain why secondary endpoints are meaningful. It does not form the basis of any claim, and Plaintiff does not challenge as misleading any statement made within it. Therefore, the Q3 2019 Earnings Call Transcript, November 4, 2019, ECF No. 52-23, is not properly incorporated by reference.

B. Puzzle Pleading

"In the securities fraud context, the term 'puzzle pleading' refers to a pleading that requires a defendant and the court to 'match up' the statements that form the basis of the plaintiff's claims

with the reasons why those statements are misleading." *Park v. GoPro, Inc.*, No. 18-cv-00193-EMC, 2019 WL 1231175, at *8 (N.D. Cal. Mar. 15, 2019) (quoting *In re Cisco Sys. Inc. Sec. Litig.*, No. 11-cv-01568-SBA, 2013 WL 1402788, at *5 (N.D. Cal. Mar. 29, 2013)). "[P]uzzle pleadings fail 'to set forth a "short and plain" statement of their claims in violation of Rule 8(a),' to 'make each allegation "simple, concise and direct"' in violation of Rule 8 and to fulfill the more exacting pleading requirements of the [PSLRA] for violations of the Exchange Act." *Primo v. Pac. Bioscis. of Cal., Inc.*, 940 F. Supp. 2d 1105, 1112 (N.D. Cal. 2013) (quoting *In re Splash Tech. Holdings, Inc. Sec. Litig.*, 160 F. Supp. 2d 1059, 1075 (N.D. Cal. 2001)). "[A] securities fraud complaint that employs a true puzzle-style pleading format will recite lengthy statements attributed to the defendants, followed by a generalized list of reasons that the statements may have been false or misleading or a generalized list of omissions that were required to make the statements not misleading." *Bos. Ret. Sys. v. Uber Techs., Inc.*, No. 19-cv-06361-RS, 2020 WL 4569846, at *4 (N.D. Cal. Aug. 7, 2020) (alteration in original) (quoting *Tarapara v. K12 Inc.*, No. 16-cv-04069-PJH, 2017 WL 3727112, at *9 (N.D. Cal. Aug. 30, 2017)).

The CAC is 194 pages long—almost certainly longer than necessary—but that fact alone does not warrant dismissal for failure to comply with Rule 8. *See In re Apple Inc. Sec. Litig.*, No. 19-cv-02033-YGR, 2020 WL 1857397, at *8 n.4 (N.D. Cal. June 2, 2020) ("Although the CCAC runs nearly 200 pages long, the Ninth Circuit has cautioned against applying a strict requirement for a 'short' statement under Rule 8 in light of the heightened pleading standards of Rule 9(b) and PSLRA."); *In re Intuitive Surgical Sec. Litig.*, 65 F. Supp. 3d 821, 831 (N.D. Cal. 2014) (describing complaint as "indisputably cumbersome, surpassing one hundred pages in length," but finding that "the breadth of the [complaint] alone does not create the type of 'puzzle-like' complaint that warrants dismissal").

The CAC is organized in a manner that generally permits the reader to connect the allegedly false or misleading statements with the reasons why Plaintiff challenges those statements. As Plaintiff explains in opposition, "[t]he alleged misstatements are organized topically, grouped according to the alleged omitted facts in each misstatement." ECF No. 56 at 19. Plaintiff arranges the challenged statements into four general categories: (1) those

concerning trial safety results; (2) those concerning whether the avacopan achieved the trial's BVAS primary endpoint and demonstrated superior remission over standard-of-care steroid therapy; (3) those concerning avacopan's ability to replace steroid therapy; and (4) those concerning the avacopan NDA and ChemoCentryx's communications with the FDA. Within each category, Plaintiff arranges the challenged statements by source and follows each set of statements from a single source with a list of reasons why all of those statements were misleading when made.

To be sure, the CAC could be organized more clearly. In some places, Plaintiff uses emphasis to indicate which parts of a lengthy statement they challenge as misleading; in others, paragraphs-long quoted statements have no emphasis at all. Plaintiff's choice to explain why *all* statements from a particular source within a particular category are false or misleading at once, rather than why *each* such statement is false or misleading, requires the reader to flip back and forth across pages of the CAC to determine which portion of a particular statement is challenged and why. *See Wenger v. Lumisys, Inc.*, 2 F. Supp. 2d 1231, 1243 (N.D. Cal. 1998) (dismissing complaint that listed challenged statements, then listed reasons why all statements were false, "in violation of the [PSLRA's] requirement that a complaint must specify the reasons why *each* statement is alleged to have been misleading"). Further, where Plaintiff alleges the same statement is misleading due to Defendants' failure to disclose several categories of omitted facts, Plaintiff reprints the statement across different sections of the CAC, instead of providing all of the reasons why a single statement is false or misleading at once. This needlessly lengthens the CAC and compromises clarity.[4]

Although the CAC is long and unwieldy, it sufficiently explains why Plaintiff alleges particular statements by Defendants were false or misleading. The CAC thus "fulfills the purpose

[4] Plaintiff also does not provide a unique identifier for each statement or even indicate the total number of statements it challenges as misleading in the CAC. Defendants have numbered the statements challenged in the CAC and appended a table of numbered statements to their motion to dismiss. ECF No. 50 at 48-72. Plaintiff argues this appendix is improper and possibly incomplete. ECF No. 56 at 20. To avoid potential confusion, the Court will identify each statement by the paragraph(s) in which it is challenged in the CAC.

of Rule 8 by putting Defendants on notice of the true substance of the claims against them." *In re Intuitive Surgical Sec. Litig.*, 65 F. Supp. 3d at 831. The Court finds that, while the CAC is "hard to follow," "it is not so deficient as to amount to puzzle pleading." *Park*, 2019 WL 1231175, at *8.

C. Material Misrepresentation or Omission

For a statement to be actionable under the PSLRA, it must be both false or misleading and material. "Under Rule 10b-5, . . . a fraudulent omission is a failure to 'state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading.'" *Wochos v. Tesla, Inc.*, 985 F.3d 1180, 1188 (9th Cir. 2021) (quoting 17 C.F.R. § 240.10b-5(b)). A statement is misleading "if it would give a reasonable investor the 'impression of a state of affairs that differs in a material way from the one that actually exists.'" *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 985 (9th Cir. 2008) (quoting *Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002)).

An omitted fact is material if there is a "substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976). "The inquiry into materiality is 'fact-specific.'" *In re Alphabet, Inc. Sec. Litig.*, 1 F. 4th 687, 700 (9th Cir. 2021) (quoting *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 43 (2011)). As such, "resolving materiality as a matter of law is generally appropriate 'only if the adequacy of the disclosure or the materiality of the statement is so obvious that reasonable minds could not differ.'" *Id.* (quoting *Fecht v. Price Co.*, 70 F.3d 1078, 1081 (9th Cir. 1995)).

Plaintiff challenges four overlapping categories of Defendants' statements as misleading due to omitted facts: (1) statements about the avacopan trial's safety results, (2) statements about the trial's efficacy results, namely statements suggesting that avacopan achieved the trial's BVAS primary endpoint and demonstrated superior BVAS remission as compared to prednisone, (3) statements about the trial's design and avacopan's ability to replace steroid therapy, and

(4) statements about the avacopan NDA and the company's communications with the FDA.[5] Plaintiff alleges that, unbeknownst to investors, Defendants were aware that trial results could not support their safety claims, that the majority of trial participants were taking steroids, that positive trial results were the result of deviations from trial protocol, and that the FDA had communicated serious concerns about the trial design. Plaintiff alleges that Defendants' failure to disclose these facts to investors rendered the challenged statements misleading.

Defendants argue that their statements were not misleading; that any alleged omissions were corrected by their public disclosures during the Class Period; that ChemoCentryx had no duty to disclose its private communications with the FDA; and that a subset of these statements are non-actionable opinion statements, statements of corporate optimism, or forward-looking statements.

1. Statements About Trial Safety Results

Plaintiff challenges over five dozen statements Defendants made about the trial's safety results during the Class Period, including that that "compelling evidence supported avacopan's superior profile of therapy versus glucocorticoid standard of care"; that "irrefutable" evidence showed "glucocorticoid toxicities were dramatically reduced"; that trial results showed "[a] statistically significant improvement in clinically validated measurements of quality of life on avacopan therapy," such as the "newly-validated glucocorticoid toxicity index" ("GTI"); that "fewer subjects [had] serious adverse events in the avacopan group" than the steroid group; and that "the number of serious hepatic function [adverse events] was 9% or 5.4% in the avacopan group versus 6% in the prednisone group," which was "not a statistically significant difference." ECF No. 47 ¶¶ 218-290.

[5] Due to the number of statements at issue, the Court must consider these statements in groups, rather than individually. *See In re Connectics Corp. Sec. Litig.*, 542 F. Supp. 2d. 996, 1006 (N.D. Cal. 2008) ("Because the volume of allegedly actionable statements is so large, the Court will not examine each statement individually but will instead group them . . . for purposes of defendants' motion to dismiss."); *In re Syntex Corp. Sec. Litig.*, 95 F.3d 922, 928 (9th Cir. 1996) ("In order to apply this abundance of recent case law to the multiplicity of allegations in the 103 page [c]omplaint, we have grouped the challenged statements made by Defendants into three areas."). The Court will group the statements into the same four categories set out in the CAC.

Plaintiff alleges such statements were misleading due to Defendants' failure to disclose the FDA's concerns about the trial. For instance, as early as November 2016, the FDA told Defendants that, though they "argued that, as replacement for glucocorticoids, [avacopan] will provide an improved benefit-risk profile through similar efficacy and less toxicity than glucocorticoids," the trial design they proposed was "likely not adequate to support such safety comparisons." *Id.* ¶ 86. The FDA later told Defendants that the trial "was not designed to assess whether replacing potential toxicity of treatment with [glucocorticoids] with potential toxicities with avacopan represents a clinical benefit to patients." *Id.* ¶ 94. The FDA also raised concerns about the study's proposed use of GTI, "markers of renal function," and other quality-of-life metrics, stating that "there does not appear to be adequate data to support the use of these endpoints to support long-term outcomes in vasculitis," and that "the clinical meaningfulness of GTI . . . has not been characterized." *Id.* ¶¶ 88-91.

Accepting all factual allegations in the CAC as true and construing the CAC in the light most favorable to Plaintiff, the Court finds that Plaintiff sufficiently pleads that the challenged statements in this category were misleading. Defendants' statements regarding avacopan's superior safety profile would give a reasonable investor the impression that the trial results could support a safety comparison between avacopan and standard-of-care steroid therapy. Defendants' statements about quality-of-life metrics would similarly suggest those metrics were meaningful. Plaintiff alleges that, in reality, the FDA had informed Defendants the trial results would not support such conclusions – an important difference to a reasonable investor. As such, Plaintiff has adequately pleaded that the challenged statements in this category were misleading.

Defendants argue any omissions were not material to investors because there was no indication that the FDA's concerns would preclude the drug's approval. An omission is material if there is a "substantial likelihood" that a reasonable investor would have viewed its disclosure "as having significantly altered the 'total mix' of information" available. *TSC Indus.*, 426 U.S. at 449. Plaintiff alleges that the FDA's undisclosed concerns about the trial's design and proposed secondary endpoints were material because they cast doubt on the safety and efficacy of avacopan, decreasing the likelihood of FDA approval with the broad label Defendants sought and limiting

how broadly the drug would be prescribed or used. Regardless of whether Defendants had any indication that the FDA's concerns would fully prevent the drug's approval, those concerns at least increased the risk that the drug would not be approved, would only be approved for a narrower label than the one Defendants predicted, or would not be as widely used by ANCA-associated vasculitis patients as Defendants suggested. Any of these risks could be important to a reasonable investor. *See In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 528 (S.D.N.Y. 2015) ("[B]ecause of the fact-intensive nature of the materiality inquiry, the Court may not dismiss a complaint 'on the ground that the alleged misstatements or omissions are not material unless they are so obviously unimportant to a reasonable investor that reasonable minds could not differ on the question of their importance.'") (quoting *Carpenters Pension Tr. Fund*, 750 F.3d 227, 235 (2d Cir. 2014)). Accordingly, the Court finds that Plaintiff has sufficiently alleged that Defendants' omissions were material.

2. Statements About Trial Efficacy Results

Plaintiff challenges over three dozen statements Defendants made regarding the trial's efficacy results. ECF No. 47 ¶¶ 291-350. Defendants repeatedly discussed the BVAS remission endpoint results, including that avacopan therapy "met" the primary endpoint of "disease remission at 26 weeks and sustained remission at 52 weeks," that patients in the avacopan arm of the trial were "sustained in remission at week 52 in a very statistically superior way to the standard-of-care arm," and that avacopan could reduce relapse risk for patients without the use of steroids. *Id.*

Plaintiff alleges these statements are misleading because Defendants failed to disclose that: (1) Defendants violated the trial protocol in analyzing trial data and, when analyzed according to protocol, avacopan was not statistically significantly superior to standard-of-care steroid therapy at either 26 or 52 weeks;[6] (2) the FDA had stated that superiority would be required to demonstrate

[6] In particular, Plaintiff alleges Defendants did not follow the trial protocol when scoring persistent vasculitis and therefore incorrectly inflated the number of patients in remission at weeks 26 and 52. Because Defendants did not disclose that the trial would not count persistent vasculitis and that BVAS remission endpoint results would therefore overestimate remission, Defendants' statements about the trial's BVAS remission results and relapse rates were misleading.

that avacopan could replace standard-of-care therapy, such that Defendants could not tout the trial's week 26 non-inferiority result without implicitly misleading investors regarding the significance of that result; (3) the FDA had warned that the relapse results Defendants described would not be statistically reliable due to trial design and analysis issues; (4) avacopan patients widely used steroids to control their vasculitis during the trial; and (5) patients in different subgroups within the standard-of-care arm received different treatments over the course of the trial, and trial results showed that avacopan was not superior to one of those subgroups. Taken as true,[7] these omissions rendered Defendants' statements about the trial's efficacy results misleading; investors were led to believe the efficacy results were far stronger and more meaningful than they actually were.

Defendants argue any omissions were not material and therefore not misleading. Defendants dispute the nature and importance of the FDA's comments, arguing Plaintiff does not allege the FDA indicated these concerns would prevent approval. As discussed above, regardless of whether the agency's concerns would preclude the drug's approval, they at least increased the risks that the drug would not be approved, would only be approved for a narrow label, or would not be as widely used by ANCA-associated vasculitis patients as Defendants estimated. Deviation from trial protocol, omission of subgroup results, or widespread use of steroids that undermined Defendants' efficacy claims would similarly increase those risks. And any of those risks could be important to a reasonable investor. *See In re Sanofi*, 87 F. Supp. 3d at 528. Accordingly, the Court finds that Plaintiff has sufficiently alleged that Defendants' omissions were material at this stage.

3. Statements About Avacopan's Ability to Replace Steroids

Plaintiff challenges nearly two dozen of Defendants' statements regarding avacopan's ability to replace steroids, including those suggesting that avacopan patients in the trial did not receive steroids and that the trial showed that avacopan could eliminate daily steroid use. ECF

[7] Defendants dispute Plaintiff's allegations that their analysis departed from trial protocol. For the purposes of evaluating a motion to dismiss, the Court assumes all well-pleaded factual allegations in the CAC are true.

No. 47 ¶¶ 351-404. Plaintiff alleges these statements were misleading because Defendants failed to disclose the extent and nature of steroid use among trial participants, including that the majority of avacopan patients were prescribed steroids to control their vasculitis during the trial; that Defendants counted avacopan patients as achieving remission even if they were prescribed steroids to control their vasculitis during the trial; and that the FDA had told Defendants the trial likely could not assess whether avacopan could be used as a replacement for steroids.

Plaintiff fails to sufficiently allege that one of the statements challenged in this category was misleading. Plaintiff challenges the following statement: "We at ChemoCentryx are entirely devoted to a different and, we believe, better approach: highly targeted, non-immunosuppressive medicines such as avacopan. *Such medicines are entirely unlike the current immune-destroying regimen of high doses of prednisone* combined with other immune system dampeners." ECF No. 47 ¶ 367 (emphasis in original).[8] Plaintiff alleges this statement was materially misleading when made because Defendants failed to disclose widespread steroid use in the trial. But the challenged statement makes no claims about the trial; rather, it describes avacopan *itself* as unlike standard-of-care steroid therapy. Because Plaintiff does not plead any omissions that would render that description false or misleading, the Court will dismiss the claims regarding this challenged statement.

Plaintiff sufficiently pleads that Defendants' omissions rendered the remainder of the statements in this category misleading: Defendants' statements led investors to believe that patients in the avacopan arm of the trial did not regularly use steroids to control their vasculitis, that avacopan achieved better remission rates than it actually did, and that trial results could meaningfully compare avacopan to steroid treatment.

Defendants argue that there was no indication that the FDA's comments would affect the drug's approval, so any omitted facts were not material. As discussed above, however, these comments increased risks, aside from approval, that could be important to a reasonable investor,

[8] Where Plaintiff emphasizes only portions of text within a specific statement challenged in the CAC, the Court assumes that Plaintiff seeks to challenge solely the emphasized portion of the statement.

so the Court finds Plaintiff has sufficiently alleged that this omission was material to survive a motion to dismiss.[9]

4. Statements About NDA and FDA Communications

Finally, Plaintiff challenges a dozen statements regarding the avacopan NDA and Defendants' communications with the FDA, including that the NDA was "supported by," "built upon," or "based on" trial results; that communications with the FDA had been "straightforward and expected"; and that the FDA had "not highlighted any particular issues that would have to be discussed" by an Advisory Committee. ECF No. 47 ¶¶ 405-428. Plaintiff alleges these statements were misleading because Defendants failed to disclose that the FDA had expressed various concerns about the trial's design and that, in light of those concerns, it might need to convene an Advisory Committee to interpret trial results.

Reviewing the CAC, the Court finds that Plaintiff fails to sufficiently plead the falsity of the following five challenged statements:

- "We are actively preparing our NDA submission to the FDA following the positive results of the Phase III ADVOCATE trial of avacopan for the treatment of ANCA vasculitis." ECF No. 47 ¶ 409.
- "The Company's NDA submission is supported by the results of its pivotal Phase III ADVOCATE trial. . . ." *Id.* ¶¶ 411, 414.
- "In July 2020, we submitted a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, for avacopan for the treatment of ANCA vasculitis in the United States. . . . Based on the success of the avacopan clinical studies in ANCA vasculitis, we filed an NDA with the FDA in July 2020." ¶ 415.
- "In early July as shown on slide 4 we submitted our new drug application to the FDA for avacopan in the treatment of patients with ANCA- associated vasculitis. . . . Our applications to regulatory agencies and our preparations for the anticipated commercialization of avacopan are built upon the key findings in the ADVOCATE pivotal trial." *Id.* ¶ 416.
- "Obviously, we have a potential path to regulatory approval as I've just laid out with some of the qualities that I've shown you from the ADVOCATE data set." *Id.* ¶ 405.

[9] Defendants also argue they publicly disclosed the trial's analysis plan and the nature and extent of steroid use, which the Court addresses in Section IV.C.6.

Plaintiff alleges that these statements are misleading due to Defendants' omission of the FDA's stated concerns about the trial's design and results. But these statements do not give investors the "impression of a state of affairs that differs in a material way" from reality. *Berson*, 527 F.3d at 985 (quoting *Brody*, 280 F.3d at 1006). These statements largely convey that ChemoCentryx submitted an NDA on the basis of trial results, and Plaintiff does not plead any facts to the contrary. That certain of these statements describe trial results as "positive" or a "success" does not modify this outcome, because a reasonable investor would assume any NDA to be based on whatever positive or successful results were achieved in a Phase III clinical trial, no matter how minimal the success. Similarly, Defendants' statement regarding a potential path to regulatory approval based on the trial data set is not misleading. Plaintiff does not plead any facts that suggest there was no path to regulatory approval for avacopan, and a reasonable investor would expect any potential path to approval to be based on Phase III trial results.

Taking all well-pleaded factual allegations as true and construing the CAC in the light most favorable to Plaintiff, the Court finds that Plaintiff has sufficiently pleaded that the remaining challenged statements in this category were misleading when made. Defendant's omissions would lead a reasonable investor to believe that the FDA had not highlighted particular concerns to Defendants that would likely need to be discussed by an Advisory Committee, while the agency had highlighted specific concerns and indicated that it might need to convene an Advisory Committee to evaluate trial results.

Defendants argue they sufficiently disclosed that the FDA might interpret trial results differently from ChemoCentryx, such that any statements about communications with the FDA would not mislead a reasonable investor. However, Plaintiff plausibly alleges that, at the time the statements were made, the FDA had already shared feedback on trial design that indicated it disagreed with Defendants' position on how trial results could be interpreted, rendering Defendants' abstract warnings of future risk insufficient. *See In re Alphabet, Inc. Sec. Litig.*, 1 F.4th at 704 ("Risk disclosures that 'speak[] entirely of as-yet-unrealized risks and contingencies' and do not 'alert[] the reader that some of these risks may already have come to fruition' can mislead reasonable investors."). The Court finds Plaintiff has sufficiently pleaded that

Defendants' omissions about the FDA's concerns are material for this stage of litigation.

The Court finds that Plaintiff has failed to adequately allege that the statements challenged at CAC ¶¶ 405, 409, 411, and 414-16 are material misrepresentations. Plaintiff has sufficiently pleaded the falsity of all other statements challenged in this category.

5. Duty to Disclose

Defendants argue they had no duty to disclose any interim communications with the FDA, including the FDA's concerns about the avacopan trial.

"Disclosure [of omitted facts] is required . . . only when necessary 'to make . . . statements made, in the light of the circumstances under which they were made, not misleading.'" *Matrixx Initiatives*, 563 U.S. at 44 (quoting 17 C.F.R. § 240.10b-5(b)). As such, "companies can control what they have to disclose under these provisions by controlling what they say to the market." *Id.* at 45. Therefore, "as long as the omissions do not make the actual statements misleading, a company is not required to disclose every safety-related result from a clinical trial, even if the company discloses some safety-related results and even if investors would consider the omitted information significant." *In re Rigel Pharms., Inc. Sec. Litig.*, 697 F.3d 869, 880 n.8 (9th Cir. 2012). "But 'once defendants cho[o]se to tout' positive information to the market, 'they [are] bound to do so in a manner that wouldn't mislead investors,' including disclosing adverse information that cuts against the positive information." *Schueneman v. Arena Pharms., Inc.*, 840 F.3d 698, 705-06 (9th Cir. 2016) (quoting *Berson*, 527 F.3d at 987).

Because the omission of adverse facts, including concerns shared by FDA representatives during interim communications with ChemoCentryx, rendered certain of Defendants' statements misleading – as the Court found above – Defendants had a duty to disclose those facts.

6. Public Disclosure of Avacopan Trial Results

Defendants argue that their statements about the results of the trial – including statements about safety results, efficacy results, trial design, and avacopan's ability to replace steroid therapy – could not mislead investors because Defendants publicly disclosed the trial results during the Class Period. Defendants announced trial results by press release on November 25, 2019, prior to the start of the Class Period; disclosed the trial design in a medical journal in April 2020;

discussed the trial design further at two scientific conferences in June 2020; then published additional trial results alongside the trial protocol and analysis plan in another medical journal in February 2021, prior to the end of the Class Period. In opposition, Plaintiff disputes the adequacy of these disclosures, arguing that Defendants did not divulge the FDA's concerns about the trial design or secondary endpoints, did not reveal the existence of serious adverse liver events, gave investors the false impression that risk of serious liver injury was not meaningfully different across trial participants, and did not reveal the nature or extent of steroid use by trial participants.

"Publicly available information cannot be a material omission under federal securities laws." *Sanchez v. IXYS Corp.*, No. 17-cv-06441-WHO, 2018 WL 4787070, at *3 (N.D. Cal. Oct. 2, 2018). Here, however, "[t]he adequacy of the disclosures Defendants point to is subject to a reasonable dispute, and the Court may not resolve factual disputes at the pleading stage." *In re Splunk Inc. Sec. Litig.*, 592 F. Supp. 3d 919, 946 (N.D. Cal. 2022); *see also Fecht*, 70 F.3d at 1081 ("[O]nly if the adequacy of the disclosure . . . is 'so obvious that reasonable minds could not differ' are these issues 'appropriately resolved as a matter of law.'") (quoting *Durning v. First Bos. Corp.*, 815 F.2d 1265, 1268 (9th Cir. 1987)); *Ganino v. Citizens Utils. Co.*, 228 F.3d 154, 167 (2d Cir. 2000) ("The truth-on-the market defense is intensely fact-specific and is rarely an appropriate basis for dismissing a § 10(b) complaint for failure to plead materiality."). Because the adequacy of Defendants' disclosures is not obvious, the Court finds that the adequacy of Defendants' disclosures is a factual issue that the Court may not resolve at this stage.

7. Non-Actionable Statements

Defendants argue that many of the statements Plaintiff challenges are non-actionable because they constitute opinions, corporate puffery, or forward-looking statements.

a. Opinions

Defendants first argue that some of the challenged statements are opinions and that Plaintiff does not sufficiently plead the falsity of those opinions.[10]

[10] Defendants identify these as Statements 11, 16, 20, 24, 26-28, 51, 61, 84, 90, 93, 99, 110, 115-116, 131-133, and 138. ECF No. 50 at 37. Based on the table Defendants provided, these statements are challenged at CAC ¶¶ 223, 405, 227, 355, 232-233, 407, 245, 367, 409, 259, 262, 322, 268, 423, 425-26, 286-87, and 289. ECF No. 50 at 48-72. Because the Court previously

As a preliminary matter, the Court must determine whether these statements are facts or opinions. "In the context of the securities laws, '[a] fact is a thing done or existing or an actual happening,'" while "'[a]n opinion is a belief, a view, or a sentiment which the mind forms of persons or things.'" *In re QuantumScape Sec. Class Action Litig.*, 580 F. Supp. 3d at 738 (N.D. Cal. 2022) (quoting *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175, 183 (2015)). "A statement of fact ('the coffee is hot') expresses certainty about a thing, whereas a statement of opinion ('I think the coffee is hot') does not." *Id.* (quoting *Omnicare*, 575 U.S. at 183).

All of the statements Defendants identify contain both facts and opinions. *See, e.g.*, ECF No. 47 ¶ 425 ("I think AdComs are the default position. . . . FDA has not highlighted any particular issues that would have to be discussed at AdCom but we're really doing a lot of intense preparation."). For several of these statements, Plaintiff challenges as misleading only the facts included in the statement, not the opinions. *See id.* ¶¶ 232, 236 (statement allegedly misleading for facts about renal safety of avacopan as compared to standard-of-care steroid therapy, not opinion about whether such results are unusual or unprecedented); *id.* ¶¶ 245-46 (statement allegedly misleading for facts about trial results, not opinion regarding the drug's value proposition); *id.* ¶¶ 259-60 (statement allegedly misleading for facts about trial results, not opinion regarding whether such results are unprecedented); *id.* ¶¶ 322-24 (statement allegedly misleading for facts regarding standard-of-care steroid therapy and relative relapse rates, not opinion regarding importance of relapse risk); *id.* ¶¶ 405-06 (statement allegedly misleading for fact about regulatory approval, not opinion regarding whether safety results are acceptable); *id.* ¶¶ 425, 427-28 (statement allegedly misleading for fact regarding FDA's statements, not opinion regarding likelihood of Advisory Committee). Because Plaintiff only challenges the factual portions of each of these challenged statements as actionable, the falsity of these statements is properly evaluated under the standard the Court applied above.

The remaining statements contain opinions that Plaintiff challenges as misleading. To

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dismissed the statements challenged at CAC ¶¶ 367 and 409, it need not consider them here.

plead the falsity of an opinion "on a theory of omission, the plaintiff must allege 'facts going to the basis for the issuer's opinion . . . whose omission makes the opinion statement at issue misleading to a reasonable person reading the statement fairly and in context.'" *In re Atossa Genetics Inc. Sec. Litig.*, 868 F.3d at 801-02 (alteration in original) (quoting *City of Dearborn Heights Act 345 Police & Fire Ret. Sys.*, 856 F.3d at 615–16). "[T]he court must ask whether the alleged omission rendered [the] opinions misleading . . . because the excluded fact shows that [the speaker] lacked the basis for making those statements that a reasonable investor would expect." *Omnicare*, 575 U.S. at 196.

Plaintiff challenges the following opinions about the avacopan trial results shared by Dr. Schall on investor calls and at conferences as misleading by omission:

- Avacopan's safety profile was "very acceptable." ECF No. 47 ¶ 223.
- "[E]vidence [from the trial] is irrefutable by any metric we looked at, the glucocorticoid toxicities were dramatically reduced. . . . [T]hat was a big deal." *Id.* ¶ 227.
- "We also checked [the box] with quality of life." *Id.* ¶ 233.
- Avacopan's quality of life results were "fundamentally important" and "really going to have a big impact on the, I think, the value proposition." *Id.* ¶ 262.
- "We had fewer adverse events and fewer serious adverse events, a very acceptable safety profile to go forward we believe and apply for approval in this indication." *Id.* ¶ 268.
- "[A]vacopan benefit-risk profile is strong" and "the secondary endpoints are important because they are, we believe, fundamentally, clinically relevant." *Id.* ¶ 286.
- "[W]e believe that the benefit risk profile for [a]vacopan is distinctly favorable in ANCA vasculitis." *Id.* ¶ 287.
- "We believe that clinically meaningful primary and secondary endpoint signals consistently favor avacopan therapy." *Id.* ¶ 289.
- "Does the ADVOCATE trial provide evidence that steroids need not be used when avacopan is available? I think in a word, yes, *resoundingly, yes*. . . . This may be the beginning of the era where *steroids go by the way of the dinosaur*." *Id.* ¶ 355 (emphasis in original).

Plaintiff alleges that these opinions were misleading when shared because Defendants failed to correct trial results for multiplicity, disclose the FDA's concerns about the trial's safety

and efficacy metrics, or disclose the FDA's concerns that the trial could not support a comparative analysis of the safety of avacopan and standard-of-care steroid treatment.

Plaintiff sufficiently alleges that these omissions render the above opinions misleading. "Reasonable investors understand that dialogue with the FDA is an integral part of the drug approval process, and no sophisticated investor familiar with standard FDA practice would expect that every view of the data taken by Defendants was shared by the FDA." *Tongue v. Sanofi*, 816 F.3d 199, 214 (2d Cir. 2016). However, a reasonable investor informed of Phase III trial results involving "clinically meaningful primary and secondary endpoint[s]" would expect that the speaker had a factual basis for their belief that such results were relevant or meaningful. When told the benefit-risk or safety profile of the drug was favorable or stronger than another treatment, such an investor would assume the trial design could support such analysis. In the context of a Phase III trial—which typically precedes the filing of an NDA—such an investor would expect that the speaker's proposed interpretation of trial results had not already been undermined by the agency tasked with evaluating the NDA. The Court finds that Plaintiff has adequately pleaded that Defendants lacked the basis for these opinions that a reasonable investor would expect, such that the above statements are misleading.

Plaintiff also challenges several of Dr. Schall's opinions about the regulatory process and FDA communications as misleading by omission:

- "*So, we really did sweep the board here*. . . . And *that takes us to a new place both with regulators*. . . So, summary, I think compelling evidence of superior profile of therapy of avacopan, *full stop*. . . . But *I think the regulatory path is clear* and I think we know what we need to do in the market place." ECF No. 47 ¶¶ 233, 407 (emphasis in original).
- "*All of our interactions* with the agency so far . . . [have] to my mind have been *straightforward and expected*." *Id.* ¶ 423 (emphasis in original).
- "[T]he review process in our opinion is going in a *very straightforward, routine manner* and I think the questions and answers we've provided in a timely fashion are again quite expected for this kind of application. So, *nothing extraordinary* to report at this point." *Id.* ¶ 426 (emphasis in original).

Plaintiff alleges that these opinions were misleading due to Defendants' failure to disclose the

FDA's concerns that the trial, as designed, might not be able to provide meaningful evidence of avacopan's safety as compared to steroids and that the safety and efficacy endpoints might not be meaningful.

The opinions challenged at CAC ¶¶ 233 and 407 – "*So, we really did sweep the board here*," "I think compelling evidence of superior profile of therapy of avacopan, *full stop*," "[the trial evidence] *takes us to a new place both with regulators*," "*I think the regulatory path is clear*" – express Dr. Schall's beliefs about the strength of the avacopan trial results and how those results would be interpreted positively by the FDA. At the time he made these statements, Dr. Schall knew that regulators doubted that the trial, as designed, could support Defendants' position. These omitted facts "call into question [Dr. Schall's] basis for offering the opinion," *Omnicare*, 575 U.S. at 194, because Dr. Schall knew that the FDA likely would not interpret the trial results as positively. Thus, while Dr. Schall may have personally held these opinions at the time he made the statements, the CAC sufficiently alleges these opinion statements were misleading.

The opinions challenged at CAC ¶¶ 423 and 426 – that "[a]*ll of our interactions* with the agency so far . . . [have] to my mind have been *straightforward and expected*," "the review process in our opinion is going in a *very straightforward, routine manner*," and that there was "*nothing extraordinary* to report" – express Dr. Schall's belief that the avacopan review process was proceeding in an ordinary manner. Defendants' omission regarding the FDA's concerns about the interpretation of trial results does not "call into question [Dr. Schall's] basis for offering" these opinions. *Omnicare*, 575 U.S. at 194. Plaintiff pleads no omitted facts that suggest that Defendants' interactions with the FDA were out of the ordinary for the review of a drug like avacopan. Plaintiff does not suggest that the types of concerns the FDA shared with Defendants were unusual, or that the review process was in any way extraordinary. Accordingly, the Court will dismiss claims about the statements challenged at CAC ¶¶ 423 and 426.

b. Corporate Puffery

Defendants argue that certain challenged statements amount to corporate puffery.[11]

[11] Defendants identify Statements 4, 11, 16-17, 20, 22, 24, 26-28, 30, 37, 52-53, 74, 81, 87-90, 92-95, 97, 99, 109, 111, 114, and 129 as non-actionable statements of corporate optimism. Per

"Statements of mere corporate puffery, 'vague statements of optimism like 'good,' 'well-regarded,' or other feel[-]good monikers,' are not actionable because 'professional investors, and most amateur investors as well, know how to devalue the optimism of corporate executives.'" *Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc.*, 759 F.3d 1051, 1060 (9th Cir. 2014) (quoting *In re Cutera Sec. Litig.*, 610 F.3d 1103, 1111 (9th Cir. 2010)). "Such statements rise to the level of materially misleading statements only if they provide 'concrete description[s] of the past and present' that affirmatively create a plausibly misleading impression of a 'state of affairs that differed in a material way from the one that actually existed.'" *In re Alphabet, Inc. Sec. Litig.*, 1 F.4th at 700 (quoting *In re Quality Sys., Inc. Sec. Litig.*, 865 F.3d 1130, 1144 (9th Cir. 2017)). "In other words, optimistic statements are *not* [non-]actionable puffery and may form a basis for a securities fraud claim where the plaintiff pleads allegations raising the inference that the defendants were aware of facts that rendered the optimistic statements false or misleading." *In re Splunk*, 592 F. Supp. 3d at 941 (emphasis in original).

Two of the statements Defendants identify constitute corporate puffery:

- "We have achieved a *major landmark* for ChemoCentryx with the submission of the NDA for avacopan in ANCA-associated vasculitis following our *highly successful* Phase III ADVOCATE trial." ECF No. 47 ¶ 412 (emphasis in original).
- "*This NDA filing I think was a great achievement*. The data, the clinical data that led to that new drug application filing, as you mentioned, came from a Phase III pivotal trial called the ADVOCATE trial. . . . So, *a lot of stunning results that was the clinical basis of the NDA that went in*." *Id.* ¶ 418 (emphasis in original).

These statements contain no concrete descriptions of the past or present that Plaintiff alleges are false or misleading. Plaintiff challenges only the emphasized phrases within the statements. The vague positive language of the challenged phrases – "major landmark," "highly successful," "great achievement," "stunning results" – is of the sort investors know to devalue. The Court thus finds that the statements challenged at CAC ¶¶ 412 and 418 constitute non-

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Defendants' appendix, those are the statements challenged at CAC ¶¶ 220, 223, 405, 224, 227, 229, 355, 232-33, 407, 298, 303, 306, 412, 257, 319, 381, 418, 261-62, 321, 384, 322, 420, 265, 266, 268, 333, 275, 337, and 284.

actionable corporate puffery and claims about these statements are therefore properly dismissed.

The remainder of the statements Defendants identify do not constitute puffery. As a preliminary matter, all of the statements convey concrete facts that Plaintiff alleges are materially misleading. *See, e.g.*, ECF No. 47 ¶ 265 (statement that trial "really changed the landscape" and "really validated our entire approach" because "a single chemoattractant inhibitor for a very complex human condition was shown to be able to derive clinical benefit across a number of endpoints"); *id.* ¶ 298 ("Gratifyingly this trial turned out really well. We hit our primary endpoints that we were aspiring to hit. You can see we were numerically superior to the active comparator standard of care control arm at Week 26, 72% versus 70%, and that was highly statistically significantly non-inferior. . . . That was not only non-inferior, it was as you can see highly significant for superiority. I have to say that probably exceeded our expectations and gratifyingly so, this has never been shown in a trial before for ANCA vasculitis."). These statements are not merely vague statements of optimism; they provide concrete descriptions of the past and present in the form of factual statements about trial results. *See In re BioMarin*, 2022 WL 164299, at *12 (statements were not "empty opinions similar to puffery" where "they were undergirded by factual assertions").

For the reasons discussed above, the allegations of the CAC raise the inference that Defendants were aware of material, adverse facts that undermined their statements about the avacopan trial results, and that Defendants' omission of these adverse facts gave investors a misleading impression of the trial results, the prospective FDA approval process, and the prospective market for avacopan post-approval. Because Plaintiff plausibly alleges that investors were not aware of these adverse facts, the Court cannot conclude as a matter of law that a reasonable investor would have understood the challenged statements as simple corporate puffery.

c. Forward-Looking Statements

Defendants argue that many of the statements Plaintiff challenges as false or misleading are forward-looking statements protected by the PSLRA's safe harbor.[12]

[12] Defendants identify statements 4, 16, 24, 28, 51, 61-62, 80, 82, 87, 90, 113, 129, 135, and 139-141 as forward-looking statements protected by the safe harbor. ECF No. 50 at 39. Per

Under the PSLRA, "a defendant will not be liable for a false or misleading statement if it is forward-looking and either is accompanied by cautionary language or is made without actual knowledge that it is false or misleading." *In re Quality Sys., Inc. Sec. Litig.*, 865 F.3d at 1141 (emphasis omitted). Forward-looking statements include those "regarding (1) financial projections, (2) plans and objectives of management for future operations, (3) future economic performance, or (4) the assumptions underlying or related to any of these issues." *Police Ret. Sys. of St. Louis*, 759 F.3d at 1058 (quoting *No. 84 Emp'r–Teamster Joint Council Pension Tr. Fund v. Am. W. Holding Corp.*, 320 F.3d 920, 936 (9th Cir. 2003)).

The statements Defendants identify as forward-looking are mixed statements. As the Ninth Circuit has explained, "a defendant may not transform non-forward-looking statements into forward-looking statements that are protected by the safe harbor provisions of the PSLRA by combining non-forward-looking statements about past or current facts with forward-looking statements." *In re Quality Systems*, 865 F.3d at 1141. "[A] concrete factual assertion about a specific present or past circumstance goes *beyond* the assertion of a future goal, and beyond the articulation of predicate assumptions, because it describes specific, concrete circumstances *that have already occurred*." *Wochos v. Tesla, Inc.*, 985 F.3d 1180, 1192 (9th Cir. 2021) (emphasis in original). "If such factual assertions are made and are false, then they are outside the safe harbor and potentially actionable." *Id.* Accordingly, "to the extent that [Defendants' statements] highlight[] [trial] results that were already available at the time, such statements are not forward-looking and therefore are not eligible for such safe harbor protection." *In re Fibrogen, Inc.*, No. 21-cv-02623-EMC, 2022 WL 2793032, at *7 (N.D. Cal. July 15, 2022) (quoting *In re Immune Response Sec. Litig.*, 375 F. Supp. 2d 983, 1034 (S.D. Cal. 2005)).

All of the allegedly forward-looking statements highlight evidence from the trial that was available to Defendants at the time the statements were made. *See, e.g.*, ECF No. 47 ¶ 336 ("Let

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Defendants' appendix, those statements are challenged at CAC ¶¶ 220, 405, 355, 233, 407, 245, 367, 409, 312, 256, 378, 317, 377, 319, 381, 262, 336, 284, 345, 348, 349, 402, and 401. Because the Court previously dismissed the statements challenged at CAC ¶¶ 367 and 409, it need not consider them here.

us be clear, the evidence from the ADVOCATE trial overall strongly indicates that avacopan has the potential to change the treatment paradigm in ANCA vasculitis. As I mentioned, the need for daily prednisone therapy is eliminated, yet symptomatic remission is as good or indeed superior with avacopan compared to prednisone therapy and people relapse significantly less.")*; id.* ¶¶ 317, 377 ("There are some other subtle but notable findings from the ADVOCATE study. One of these, for example, is that patients on avacopan therapy performed very well in the second six months of the trial. During this period, avacopan was essentially a monotherapy since the standard concomitant background therapies such as cyclophosphamide or rituximab have ceased. The data suggests that avacopan alone may suffice in controlling ANCA vasculitis over time, perhaps without the need for repeated administrations of background immunosuppressant drugs such as rituximab."). These statements mix future-looking statements with concrete assertions regarding the results of the avacopan trial.

Accordingly, if Plaintiff has pleaded sufficient facts to establish that these assertions are false or misleading, these statements are outside the safe harbor and potentially actionable. For the reasons discussed above, Plaintiff has sufficiently alleged that Defendants were aware of and concealed adverse facts that gave investors a misleading impression of the trial results, the prospective FDA approval process, and the prospective market for avacopan post-approval. Thus, the these statements are not protected by the PSLRA's safe harbor.

D. Scienter

To establish scienter, the complaint must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u–4(b)(2)(A). The required state of mind is "a mental state that not only covers 'intent to deceive, manipulate, or defraud,' but also 'deliberate recklessness[.]'" *Schueneman*, 840 F.3d at 705 (internal citation omitted). Deliberate recklessness is "'an *extreme* departure from the standards of ordinary care,' which 'presents a danger of misleading buyers or sellers that is either known to the defendant or is so *obvious* that the actor must have been aware of it.'" *In re Alphabet, Inc. Sec. Litig.*, 1 F. 4th at 701 (emphasis in original) (quoting *Nguyen v. Endologix, Inc.*, 962 F.3d 405, 414 (9th Cir. 2020)). "Facts showing mere recklessness or a motive to commit fraud and opportunity

to do so provide some reasonable inference of intent, but are not sufficient to establish a strong inference of deliberate recklessness." *In re VeriFone Holdings, Inc. Sec. Litig.*, 704 F.3d 694, 701 (9th Cir. 2012).

The "strong inference" required by the PSLRA "must be more than merely 'reasonable' or 'permissible'—it must be cogent and compelling, thus strong in light of other explanations." *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 324 (2007). "A court must compare the malicious and innocent references cognizable from the facts pled in the complaint, and only allow the complaint to survive a motion to dismiss if the malicious inference is at least as compelling as any opposing innocent inference." *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 991 (9th Cir. 2009). In evaluating whether a complaint satisfies the "strong inference" requirement, courts must consider the allegations and other relevant material "holistically," not "scrutinized in isolation." *In re VeriFone Holdings*, 704 F.3d 694, 701-02 (9th Cir. 2012).

Considered holistically, the allegations in the CAC raise a strong inference that Dr. Schall "at least with deliberate recklessness, misled investors" by omitting adverse facts.[13] ECF No. 47 at 196. Plaintiff alleges that Dr. Schall was personally aware of the FDA's concerns regarding the trial's design and how its results could be interpreted. A former employee witnessed ChemoCentryx's most senior medical executive repeatedly discussing two serious adverse liver events with Dr. Schall, neither of which was publicly disclosed during the Class Period.[14] As the

[13] A corporation may only have scienter through its employees, and the scienter of a senior controlling officer may be attributed to the corporation itself if the officer is acting within the scope of their apparent authority. *In re Alphabet, Inc. Sec. Litig.*, 1 F.4th at 705. No party suggests that Dr. Schall was acting outside his apparent authority in making the challenged statements. Thus, the scienter of Dr. Schall is attributable to ChemoCentryx.

[14] Defendants suggest that the allegations of the confidential former employee, "at most . . . show an internal debate about the interpretation of particular safety events," and do not support an inference of scienter. ECF No. 50 at 43. Defendants cite *Kovtun v. VIVUS, Inc.*, No. 10-cv-04957-PJH, 2012 WL 4477647, at *18 (N.D. Cal. Sept. 27, 2012), in which the court found that confidential witness statements from low-level employees did not support scienter, noting that "there is nothing ominous or even surprising about employees of a pharmaceutical company that is developing a new drug engaging in discussions about safety issues. *Id.* The court noted that "nowhere does plaintiff allege, for example, that a [confidential witness] reported to upper management about a particular result of a clinical trial . . . and that upper management proposed (or agreed) to conceal this result from the public, or in fact did conceal it." *Id.* But that is precisely what Plaintiff alleges occurred here: Dr. Schall, the CEO and public face of ChemoCentryx, was directly informed of the risks associated with two serious adverse liver events

President and CEO of a small company with no drugs on the market, it is implausible that Dr. Schall would not have been aware of the progress of a Phase III trial for the company's most promising drug in development. *See In re BioMarin*, 2022 WL 164299, at *14 ("notable" allegation that a drug "was going to be a significant and lucrative product" and provide a majority of drugmaker's revenue contributed to finding of scienter).

It is similarly implausible that Dr. Schall would not have known he was misleading investors by omitting adverse facts. Dr. Schall publicly acknowledged investor "excitement" about avacopan. ECF No. 47 ¶ 41. He repeatedly discussed the trial's safety and efficacy results, in detail, with investors throughout the Class Period, opining on the significance of particular data. Dr. Schall was experienced in the field of drug development and understood the obvious risk that omission of adverse facts would mislead investors about the chances that avacopan would obtain FDA approval, be approved for a broad label, or meet Defendants' stated revenue projections.

Plaintiff also alleges that Dr. Schall was financially motivated to mislead investors regarding the strength of the trial results due to ChemoCentryx's financial circumstances. Though not independently "sufficient to establish a strong inference of deliberate recklessness," "facts showing . . . a motive to commit fraud and opportunity to do so may provide some reasonable inference of intent." *In re Silicon Graphics Inc. Sec. Litig.*, 183 F.3d 970 (9th Cir. 1999), *abrogated on other grounds by S. Ferry LP, No. 2 v. Killinger*, 542 F.3d 776, 784 (9th Cir. 2008). Plaintiffs allege that Dr. Schall sought "to conceal, for as long as possible, the truth about the ADVOCATE results . . . in order to buy time and secure the financing needed to keep the [c]ompany afloat, attempt to persuade the FDA to change its views, and bring ChemoCentryx's remaining pipeline drugs as far along in development as possible." ECF No. 47 ¶ 213.

In particular, Plaintiff alleges that, by the end of 2019 – immediately prior to the Class Period – "ChemoCentryx had an accumulated deficit of $430 million." ECF No. 47 at 67. ChemoCentryx was fully reliant on investor capital to cover rising operating costs, and Plaintiff alleges Dr. Schall mislead investors in order artificially inflate ChemoCentryx's stock price for the

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by other high-ranking employees of the company, then concealed those events from investors.

June 2020 public offering, which would raise sufficient funds to continue operations. The Company raised $325 million dollars in its that public offering, which was the largest in its history. Plaintiff alleges that investors' confidence in the future value of avacopan, as reflected in ChemoCentryx's stock price, was uniquely critical to the company's survival during the Class Period; without any products on the market, ChemoCentryx was entirely reliant on investor capital to bring avacopan to market and continue developing the other drugs in its research pipeline. In short, Plaintiff alleges that Defendants were motivated to mislead investors because the continued existence of the company was at stake.

Considered as a whole, these allegations raise a strong inference of deliberate recklessness that is "at least as compelling" as any "opposing innocent inference."[15] *Zucco Partners*, 552 F.3d at 991. Taking Plaintiff's allegations as true, it is implausible that Dr. Schall would not know about the omitted facts. It is similarly implausible that Dr. Schall would not know that the omission of such facts would mislead investors regarding trial results: the omitted facts

[15] Plaintiff also alleges that Dr. Schall's stock sales during the Class Period support an inference of scienter. Dr. Schall sold nearly 20 percent of his stock holdings in ChemoCentryx during the Class Period, approximately four times as much as he sold during the Control Period. Defendants argue that the fact that these stock sales were made according to a pre-planned 10b5-1 trading plan rebuts a potential inference of scienter. Defendants are correct that stock "sales according to pre-determined plans may 'rebut [] an inference of scienter'" because the sales are non-discretionary, and thus unlikely to be made pursuant to later-acquired insider information. *Metzler Inv. GMBH*, 540 F.3d at 1067 n.11 (alteration in original). However, because it is not clear that *all* of Dr. Schall's stock sales during the Class Period were made pursuant to a trading plan adopted prior to the Class Period, the fact that these sales were made according to a trading plan does not rebut an inference of scienter. *See Azar v. Yelp, Inc.*, No. 18-cv-00400-EMC, 2018 WL 6182756, at *18 (N.D. Cal. Nov. 27, 2018) (sales made according to pre-planned trading plan do not rebut scienter where "nothing before the [c]ourt establishe[d] when precisely the trading plan was adopted"). Further, where a corporate officer retains control over the timing of public disclosure of adverse facts – and withholds such disclosure until after their pre-planned stock sales have occurred – such sales may still support a finding of scienter. *See In re BioMarin*, 2022 WL 164299, at *14 (noting that, while pre-planned stock sales "were nondiscretionary[,]. . . concealing the negative information before the sale and setting the sale to occur prior to [disclosure] *were* discretionary choices, so it is sufficient at the pleadings stage to contribute to the plausibility of the scienter allegations"). The fact that Dr. Schall's stock sales were made pursuant to a pre-planned trading plan does not rebut an inference of scienter in this context. However, a corporate officer's sale of just 20 percent of their holdings is generally not sufficient, without more, to infer scienter. *See, e.g., Metzler Inv. GMBH v. Corinthian Colls., Inc.*, 540 F.3d 1049, 1067 (9th Cir. 2008) (finding no scienter when "only" 37 percent of holdings were sold during the Class Period). Given the relatively small proportion of holdings sold during the Class Period, Dr. Schall's stock sales do not support an inference of scienter.

undermined the safety and efficacy results that Dr. Schall repeatedly discussed throughout the Class Period and that would form the basis of the avacopan NDA.

Defendants suggest Plaintiff's theory of motive is illogical because "Defendants would not have dedicated [] tremendous amounts of resources necessary to develop avacopan if they knew concerns about the [] trial would jeopardize regulatory approval." ECF No. 50 at 46. *See Nguyen*, 962 F.3d at 415 (finding implausible plaintiff's theory that a medical device company promised FDA approval that it knew would not occur in order to temporarily inflate its stock price). Here, Plaintiffs' theory is not that Defendants knew that the FDA would withhold approval, but rather that Defendants knew of and concealed adverse facts regarding trial results from investors in order to buy time and finance the company's operations while trying to alter the potential effect of those adverse facts on the NDA process. This motive is plausible. *See, e.g.*, *In re BioMarin*, 2022 WL 164299, at *14 (finding plausible motive where "the allegations are not that defendants were *convinced* the FDA would deny approval, it is that they withheld important *warning signs* from the market") (emphasis in original); *City of Sunrise Firefighters' Pension Fund v. Oracle Corp.*, 527 F. Supp. 3d 1151, 1185 (N.D. Cal. 2021) (finding plausible motive where "Plaintiff does not allege that Defendants engaged in a fraud scheme to cover up the inevitable reveal of a critical problem . . . [but] that Defendants attempted to buy themselves time" to turn around flagging sales). Dr. Schall may have truly believed Defendants could successfully convince the FDA that the omitted adverse facts should not affect the drug's approval or label, such that investors would not suffer the losses alleged here. Or Dr. Schall may have suspected that Defendants might not succeed in their efforts to change the agency's mind, but that the funds raised in the interim would permit the company to continue developing other drugs as future sources of revenue. Either way, the Court finds that Plaintiff's theory of motive is plausible.

E. Sections 20(a) and 20A

"To establish a cause of action under [Section 20(a)], a plaintiff must first prove a primary violation of underlying federal securities laws, such as Section 10(b) or Rule 10b-5, and then show that the defendant exercised actual power over the primary violator." *In re NVIDIA*, 768 F.3d at 1052. Similarly, to state a claim under Section 20A, "the plaintiff must first plead 'a predicate

insider trading violation of the Exchange Act." *In re Volkswagen "Clean Diesel" Mktg., Sales Practices, & Prods. Liab. Litig.*, 328 F. Supp. 3d 963, 987 (N.D. Cal. 2018).

Plaintiff asserts a Section 20(a) claim against Dr. Schall based on allegations that he exercised influence and control over the public statements made by ChemoCentryx – including by speaking to investors on the company's behalf – and that those statements artificially inflated the company's stock price. Plaintiff further asserts a Section 20A claim against Dr. Schall based on allegations that he sold 900,000 shares of common stock in the company while in possession of material, nonpublic information he had a duty to disclose.

The only basis Defendants advance for dismissing Plaintiff's Section 20(a) and 20A claims is that Plaintiff has failed to state a predicate claim. Having found that Plaintiff has sufficiently pleaded Section 10(b) violations with regard to the majority of the statements challenged in the CAC – all but those challenged at CAC ¶¶ 367, 405, 409, 411-12, 414-16, 418, 423, and 426 – the Court denies Defendants' motion to dismiss Plaintiff's Section 20(a) and 20A claims to the extent they are predicated on those violations of Section 10(b).

CONCLUSION

Defendants' motion to dismiss is granted in part. Plaintiff has not sufficiently alleged the falsity of the statements challenged at CAC ¶¶ 367, 405, 409, 411-12, 414-16, 418, 423, and 426. Plaintiff's Section 10(b) claims based on those statements are dismissed with leave to amend. To the extent Plaintiff's Section 20(a) and 20A claims are predicated on the dismissed Section 10(b) claims, Plaintiff's Section 20(a) and 20A claims are also dismissed with leave to amend.

Leave to amend is granted solely to cure the deficiencies identified in this order. Any amended complaint shall be filed within 28 days.

IT IS SO ORDERED.

Dated: February 23, 2023

JON S. TIGAR
United States District Judge